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27123	7590	11/21/2007		
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	
			NOTIFICATION DATE	DELIVERY MODE
			11/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/531,698

Applicant(s)

SHEMER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/18/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the strap as claimed in Claim 4 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show a strap as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP §

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608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The use of "hanger-like" renders the claim indefinite since it is unclear what a "hanger-like" element exactly is within the realm of the current invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-7, 14-18, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama et al (5,730,149).

Nakayama et al disclose a toilet mounted urinalysis unit and further disclose a collection and sampling subunit; an electronics subunit; a first communication link for data transfer between the collection and sampling subunit and the electronics subunit; means for removably fastening the collection and sampling subunit inside a toilet bowl; a wall unit having a second communication link for data transfer between the wall unit and the toilet unit, the wall unit further includes means for storing data, and processing data to determine if changes have occurred in the at least one measured characteristic of urine; a flexible strap; the means for removably fastening is a rigid element positionable on the lip of a toilet; the means for removably fastening is a hanger-like element; a sample cell and a means for measuring conductivity; a plurality of detectors; the collection and sampling subunit, the electronics subunit and the communications link therebetween the toilet unit are integrated into a single unit; the electronics subunit

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includes a processing unit, a communications link to the wall unit, and a power supply; the power supply (68) is a battery; the wall unit includes a processing unit, a memory, a display, a means for inputting information and a communications link to the toilet unit; the communications link between the wall unit and the toilet unit is a wireless link (Figure 1 does not show a wired connection, therefore it is assumed that the connection is wireless); and the wall unit is detachable, transportable and usable with a plurality of sanitary installations. See Abstract; Figure 1-3, 20; Column 9, lines 46-67; Column 10, lines 1-7; Column 11, lines 34-39; Column 16, lines 14-18 and 30-35; Column 17, lines 43-50; Column 19, lines 54-58 and 65-67; and Column 20, lines 1-2.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 1 above, and further in view of Ackerman (2002/0026111 A1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis but fail to disclose the system further includes an output means operative in response to a change in the measured characteristic of urine, the change being greater than a

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predetermined threshold value, thereby providing an output indication indicating that the individual requires further examination; and the output means includes an alarm.

Ackerman discloses a means for monitoring glucose concentration in a physiological fluid and further discloses the system further includes an output means operative in response to a change in the measured characteristic of urine, the change being greater than a predetermined threshold value, thereby providing an output indication indicating that the individual requires further examination; and the output means includes an alarm. See Paragraphs 0011, 0022-0024, 0026, 0028, 0082 and 0165-0167.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the use of monitoring the glucose concentration and comparing it to a threshold, as per the teachings of Ackerman, since it is well known to monitor glucose concentrations and compare the measured concentration against a threshold value to determine if the patient requires medical assistance.

9. Claims 8, 19, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 1 above, and further in view of Saito et al (5,119,829).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis utilizing multiple detectors, but fail to disclose a single light source and a plurality of detectors; the communications link between the wall unit and the central computer includes a wired link.

Saito et al disclose a toilet based urinalysis means and further disclose a single light source; the communications link between the wall unit and the central computer includes a wired link. See Column 6, lines 47-49; and Column 15, lines 38-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the use of a light source for analysis, as per the teachings of Saito et al, since it would provide another means of analyzing the urine sample. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a wireless link between the electrical components of the current invention, since it is well known to utilize either a wired or wireless communications link between electrical components. It also would have been obvious to utilize a battery as a power source for the wall unit, since the power source would have to be either a battery or house current.

10. Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 7 above, and further in view of Hough et al (6,261,522 B1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis, but fail to disclose a plurality of light sources and a plurality of detectors.

Hough et al disclose a spectrophotometric apparatus and further disclose a plurality of light sources (30) and a plurality of detectors (32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include a plurality of light

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sources and a plurality of light detectors, as per the teachings of Hough et al, since it would provide another means of analyzing the urine sample.

11. Claims 25-29 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) in view of Ackerman (2002/0026111 A1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis and further discloses positioning a means for collecting and measuring a characteristic of urine in a toilet bowl; collecting urine; measuring the value of the characteristic of the collected urine; identifying the user; measuring the concentration of at least one constituent of the urine; measuring the amount of at least one constituent of the urine; and measuring the conductivity of the urine. See Abstract; Figure 1-3, 20; Column 9, lines 46-67; Column 10, lines 1-7; Column 11, lines 34-39; Column 16, lines 14-18 and 30-35; Column 17, lines 43-50; Column 19, lines 54-58 and 65-67; and Column 20, lines 1-2.

Nakayama et al however fail to disclose comparing the measured value to a threshold value; indicating the measured value exceeds the threshold value; testing the reasonableness of the measured characteristic; measuring the pH of the urine; comparing the measured value to a threshold value based on the average of similar measurements over a period of time; the predetermined period of time has changeable start and end dates or fixed start and end dates; and comparing at least two characteristics of the body fluid.

Ackerman, as discussed above, disclose a means for measuring glucose of a body fluid and further disclose comparing the measured value to a threshold value;

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indicating the measured value exceeds the threshold value; testing the reasonableness of the measured characteristic; measuring the pH of the urine; comparing the measured value to a threshold value based on the average of similar measurements over a period of time; the predetermined period of time has changeable start and end dates or fixed start and end dates; and comparing at least two characteristics of the body fluid. See Paragraphs 0011, 0022-0024, 0026, 0028, 0082 and 0165-0167.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the ability to compare the measured concentration against a threshold value, as per the teachings of Ackerman, since it would provide a means of determining if the patient requires medical assistance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a standard deviation or a percentage as the threshold value, since it is well known to utilize such values to determine if the measured quantity is an abnormal or normal measurement.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) in view of Ackerman (2002/0026111 A1) as applied to claim 25 above, and further in view of Saito et al (5,119,829).

Nakayama et al and Ackerman, as discussed above, disclose means for measuring characteristics of urine, but fail to disclose the measurement of the temperature of the urine.

Saito et al, as discussed above, disclose a toilet based urinalysis means and further disclose measuring the temperature of urine. See Column 9, lines 17-22.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nakayama et al and Saito et al to include the ability to measure the temperature of urine, as per the teachings of Saito et al, since it would provide a means of determining if the patient has an infection or fever.

Allowable Subject Matter

13. Claims 9, 11 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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AU 3736